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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/677,976 10/02/00 KAFRISSSEN

M ORT-1316

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HM22/1102

EXAMINER

DEWITTY, R

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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**Office Action Summary**

Application No.

09/677,976

Applicant(s)

KAFRISSEN ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claim 21 is pending in the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Prevention is critical or essential to the practice of the invention; they are included in the claim as not enabled by the disclosure. Based on Applicant's disclosure, one with ordinary skill in the art would not know how to prevent the disorders. Specifically, Applicant's does not teach subjects predisposed to develop cancer, either genetically or otherwise(lifestyle).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claim 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Mortimer further in view of Tepic et al. (U.S. Pat. No. 5,851,985).

Mortimer (GB 2,131,292) relates to progestational pharmaceutical formulations and their use. Mortimer teaches that many synthetic compounds are known which are related to progesterone and exhibit similar hormonal activity (page 1, lines 36-37).

Progestational agents are known to cause desquamation of superficial cells of the vaginal mucosa, inhibit ferning of the cervical mucus, and induce withdrawal bleeds in oestrogen primed women (page 1, lines 46-48).<sup>4</sup> Mortimer teaches that patients for whom progestational agent therapy is appropriate would benefit from treatment with folic acid (page 1, line 57-58). Examples of synthetic progesterone suitable for use in the invention include: Norgestrel and Norethisterone (page 2, lines 25 and 27).

As both Norgestrel and Norethisterone as listed as suitable compounds in the instant application (see page 19 and 20), the instant claim is anticipated.

Mortimer, however, does not teach the use of folic acid in the treatment of cervical dysplasia or cervical carcinoma.

*In addition to folic acid and biotin*  
Tepic et al. relates to methods and compositions for the treatment of tumors by systemic deprivation of amino acid. In vitro studies of Tepic's research focused on the use of HeLa Cells (human cervical carcinoma). Results showed that using after using the composition, 96 hours later to be exact, all HeLa cells were dead (col. 7, lines 45-55). In preparing the concentrate solutions of the Tepic's invention, folic acid and d-biotin were dissolved in 25 ml of NaOH and added to the container.

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Based on the above teachings, one with ordinary skill in the art would have been motivated to utilize an oral contraceptive and folic acid in a composition for the treatment of cervical carcinoma. Motivation to do such would have arisen out because it is taught that folic acid is useful for those for whom oral contraceptives are needed, and folic acid has beneficial effects, including being used to kill cervical carcinoma cells.

***Response to Arguments***

3. Applicant's arguments with respect to claim 21 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
October 31, 2001

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616